

REMARKS/ARGUMENTS

Reconsideration of this application is requested. Claims 25-29 and 48-79 are in the case.

I. THE OBVIOUSNESS REJECTION

Claims 25-29 and 48-79 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over PDR for Herbal Medicines (1998) and WO 94/25041 to Koniger et al, Derwent Abstract and Machine Translation in view of JP 07-285830 to Ramin, translated as U.S. Patent 5,667,768, and Trimuyadi et al (Conference of the Asian Societies, 2001). The rejection is respectfully traversed.

The claimed invention is directed to a method of treatment of onychoschizia in a patient in need of such treatment. The method comprises administering to the patient a topical composition comprising (a) at least one herb extract from the genus *Equisetum*, and (b) at least one film forming agent.

On page 3 of the outstanding Official Action, it is asserted that:

“Accordingly, the topical use of *Equisetum* (including in the form of an extract thereof) for treating brittle nails (whatever the underlying pathology) -including brittle nails widespread and commonly caused by onychoschizia or brittle nails resulting from and/or commonly associated with onychomycosis, would clearly have been obvious based upon the beneficial teachings provided by the primary references cited above, for the reasons set forth in the previous Office action.”

As evidenced below, the cited documents do not suggest that an extract from *Equisetum* may be beneficial for the treatment of onychoschizia. Moreover, there is no suggestion in any of the cited documents that a topical composition comprising such extract would be efficacious in the treatment of onychoschizia. In this regard, attention

is directed to the attached executed Rule 132 declaration of Federico Mailland (the Mailland declaration). This is discussed below.

As described in the present specification (pages 3 and 4), and confirmed by the Mailland declaration referring to Enclosure 1 (submitted with the prior response, and a further copy is attached to the Mailland declaration), onychoschizia is not a generic condition of nail brittleness, but rather a specific and well-characterized pathology of the nails, wherein the distal portion of the nail splits horizontally. The Mailland declaration states that while PDR for Herbal Medicine (PDR) reports that *Equisetum* may be used for the treatment of "brittle finger nails and loss of hair", the efficacy of such use "is not proven" and, moreover, there is no suggestion in PDR to apply *Equisetum* topically onto nails.

With regard to Koniger, the Mailland declaration notes that while Koniger discloses the use of *Equisetum* extracts in the treatment of onychomycosis, there is no mention in this reference of treatment of brittle and splitting nails. The Mailland declaration goes on to state that onychomycosis and onychoschizia are "different and unrelated conditions", and require "two completely different treatments". In particular, as stated in the Mailland declaration referring to Enclosure 2 (attached to the prior response and a further copy attached to the Mailland declaration), onychomycosis is a fungal infection of the nails, caused by specific microorganisms and its treatment requires the use of antimycotic agents. In this pathology, the nail structure is damaged by the fungi that grow inside the nail and render the nail more fragile. The Mailland declaration states that onychomycosis is never a cause of onychoschizia, but it is

frequently a cause of onycholysis, i.e., a detachment of the full nail plate from the nail bed.

The Mailland declaration then discusses Example 10 of the present application which describes the results of a study of subjects previously affected by onychomycosis. The Mailland declaration notes that, after treatment with the claimed composition, no effect was seen in these subjects regarding onycholysis, whereas a definite improvement was recorded with onychoschizia (a significant improvement ($p<0.001$) was observed compared to untreated nails).

In summary, onychoschizia is not a generic condition of nail brittleness, but rather a specific and well-characterized pathology of the nails, wherein the distal portion of the nail splits horizontally. This is described in the present specification at paragraphs 0008 and 0012. The four cited references, taken alone or in combination, contain no suggestion of this pathology and none of them would lead one of ordinary skill to believe that *Equisetum* could be beneficial in the treatment of onychoschizia. Moreover, the cited references do not contain any suggestion that would have motivated the skilled person to believe that the topical treatment of nails with an extract from *Equisetum* may improve brittleness and splitting of the nails.

In view of the above, since onychomycosis and onychoschizia are quite different and unrelated conditions, requiring completely different treatments, it is clear that one of ordinary skill would not have been motivated to topically use an extract of *Equisetum* to treat onychoschizia based on Koniger or the other cited art. This is further confirmed by the experimental section of the present application.

MAILLAND
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Based on the above, it is clear that there would have been no motivation for one of ordinary skill in the art to arrive at the presently claimed invention in light of the cited references. Absent any such motivation, a *prima facie* case of obviousness has not been generated in this case. Withdrawal of the obviousness rejection is respectfully requested.

II. PRIORITY CLAIM

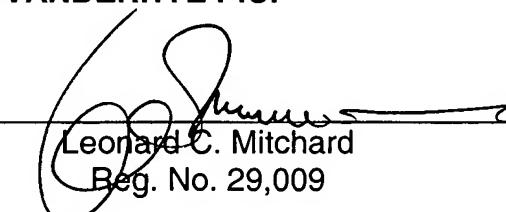
It is again noted that Boxes 12(c)(3) are crossed on the first page of the Action. A certified copy of the underlying EP priority document 03076934.3 filed June 23, 2003 was forwarded to the US Designated Office. For completeness, a true copy of the EP priority document 03076934.3 filed June 23, 2003 is attached hereto. Acknowledgement of receipt of this document is respectfully requested.

III. CLAIM AMENDMENTS

Minor clarifying amendments have been made to the claims. No new matter is entered. Favorable action is awaited.

Respectfully submitted,

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Attachments: Executed Mailland Declaration, and noted attachments thereto; RCE; copy of EP priority document 03076934.3 filed June 23, 2003; requisite fees